

## REMARKS

Reconsideration and allowance in view of the foregoing amendments and the following remarks are respectfully requested.

Claims 19-25 remain pending in the present application. Claims 1-18 were cancelled in a previous amendment.

### I. Objections to the Claims

Claims 19 and 24 are objected to due to minor informalities. Accordingly, these claims have been amended above, as suggested by the Examiner, to correct these informalities. Claims 22 and 25 were also amended to correct minor informalities. Applicant respectfully requests that the above amendment to the claims be entered and the objections withdrawn.

### II. Rejection Based on the Prior Art

Claims 19, 21, 24, and 25 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,148,802 to Sanders et al (“the ‘802 patent”). Applicant respectfully traverses this rejection for the reasons presented below.

The present invention provides an automatic ON/OFF capability so that the pressure support system turns itself ON when a patient dons the patient interface device and begins breathing into it. Otherwise, the system remains OFF. The Examiner interprets the claims to correspond to a feature described in the ‘802 patent, in which the pressure delivered to the patient transitions from a relatively low level (EPAP) to a relative high level (IPAP) when the pressure support system detects that the patient has completed an expiratory phase of a respiratory cycle and has begun an inspiratory phase. As it is not the intention of the present pending claims to cover a bi-level mode of pressure support, but to cover an automatic ON/OFF capability, independent claim 19 has been amended above to clarify the features of the present invention.

Claim 19, as amended, recites that the processor activates the pressure generating system from a first state - in which the pressure generating system is substantially inactive - to a second state - in which the pressure generating system is operated in accordance with a pressure support mode - when the processor determines that a patient is breathing into the patient

interface. Applicant notes that the pressure support mode in the second state is any mode of pressure support therapy, including a continuous positive airway pressure (CPAP) therapy, a bilevel therapy that includes the IPAP and EPAP pressures delivered during inspiration and expiration, respectively, a variable pressure mode of support, such as an auto-titration mode where the pressure delivered to the patient is adjusted by the pressure support system, or any combination thereof. Applicant respectfully submits that the transitions between IPAP and EPAP taught by the '802 patent do correspond to the transition between the claimed first state, which is an inactive mode where no therapeutic mode of pressure support is administered to the patient, and a second state, which is an activated state in which the pressure generating system provides a pressure support therapy.

For the reasons presented above, applicant respectfully submits that independent claim 19 is not anticipated or rendered obvious by the cited references. In addition, claims 21, 24, and 25 are also not anticipated or rendered obvious due to their dependency from independent claim 19. Accordingly, applicant respectfully request that the above rejection of claim 19, 21, 24, and 25 be withdrawn.

Claim 20 stands rejected under 35 U.S.C. § 103 as being unpatentable over the '802 patent in view of U.S. Patent No. 4,345,592 to Giorgini et al. ("the '592 patent"). Applicant respectfully traverses this rejection for the reasons presented below.

The '592 patent discloses a firefighter's oxygen delivery system that includes a pneumatically actuated gas flow shut-off that reduces the supply of oxygen from the oxygen tank to the mask if the mask becomes dislodged from the firefighter's face. According to the '592 patent, this feature prevents an excessive loss of oxygen from the limited amount of oxygen in the storage tank in the event the firefighter's mask becomes dislodged and the firefighter is unable to manually shut off the oxygen flow to the mask.

The Examiner first alleges that one skilled in the art would be motivated to combine the teachings of the '592 patent with that of the '802 patent to prevent wasting of breathing gas. Applicant respectfully disagrees with the basis of the proposed rational for combining these references. The '802 patent teaches a pressure support system that typically

users ambient air as the source of gas. Therefore, there is little or no need for those skilled in the art to worry about gas conservation, and, hence, look to the '592 patent for a solution. That is, preventing the wasting of gas was not much of a problem, if at all, for those using the pressure support system, because, unlike a firefighting, system there is an unlimited supply of breathing gas available to the pressure support system. Because there would be no reason to attempt to seek a solution to something of little or no concern, there is no motivation to combine the teachings of the '592 patent with those of the '802 patent.

The Examiner next alleges that one skilled in the art would be motivated to combine the teachings of the '592 patent with that of the '802 patent to prevent the patient from being subject to dangerously high gas pressures. Applicant respectfully submits that nothing in either the '802 patent or the '592 patent suggests that either system would deliver a dangerously high pressure. Quite the contrary, the '802 patent uses a pressure controller to ensure that the proper pressures are applied to the patient. Therefore, the device taught by the '802 patent does not need an automatic shut off capability for the safety reason suggested by the Examiner.

Even if the teachings of the '592 patent and the '802 patent were combined, which applicant does not admit is possible or suggested, the resulting combination would not include the features recited in amended independent claim 19. For example, the combination of the of the '592 patent and the '802 patent would not use breath-detection as the criteria for activating the pressure support system, as recited in claim 19 of the present application. Instead, the resulting device but would use the pneumatic gas flow cutoff system of the '592 patent. According to the '592 patent, if the pressure inside the mask drops below a threshold, which would happen if the mask is dislodged, a pressure actuated shut-off valve at the mask is actuated to reduce the flow of oxygen to the mask. It can be readily appreciated that the breath monitoring technique recited in amended independent claim 19 to determine whether to activate the pressure generating system is wholly dissimilar to the pressure threshold technique taught by the '592 patent.

Those skilled in the art understand that the breathing detection taught by the '802 patent is used to control the pressure levels delivered to the patient during each phase of the respiratory cycle. Nothing in the '802 patent or the '592 patent teaches or suggests using breathing detection to control the actuation of the pressure generating system. Nor would this be possible, because the pressure threshold shut-off mechanisms taught by the '592 patent are based on monitoring the pressure against a threshold - not for monitoring based on pressure variations.

For the reasons presented above, applicant respectfully submits that amended independent claim 19 is not rendered obvious by the cited references. Thus, claim 20 is also not rendered obvious due to its dependency from independent claim 19. Accordingly, applicant respectfully requests that the above rejection of claim 20 be withdrawn.

Claims 22 and 23 stand rejected under 35 U.S.C. § 103 as being unpatentable over the '802 patent in view of U.S. Patent No. 5,117,819 to Servidio et al. ("the '819 patent"). Applicant respectfully traverses this rejection for the reasons presented below.

The '819 patent is cited for the proposition that it is known to increase the pressure of gas over a period of time, i.e., to "ramp" the pressure. This reference, however, does not teach or suggest the automatic ON/OFF capability discussed above. Therefore, independent claim 19 is not rendered obvious by the cited references, including the '819 patent. Claims 22 and 23 are also not rendered obvious due to their dependency from independent claim 19. Accordingly, applicant respectfully requests that the above rejection of claims 22 and 23 be withdrawn

This response is being filed within the three-month statutory response period which expires on June 22, 2004. In addition, no additional claim fees are believed to be required as a result of the above amendments to the claims. Nevertheless, the Commission is authorized to charge the any fee required under 37 C.F.R. §§ 1.16 or 1.17 to deposit account no. 50-0558.

All objections and rejections have been addressed. It is respectfully submitted that the present application is in condition for allowance and a Notice to the effect is earnestly solicited.

Respectfully submitted,

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